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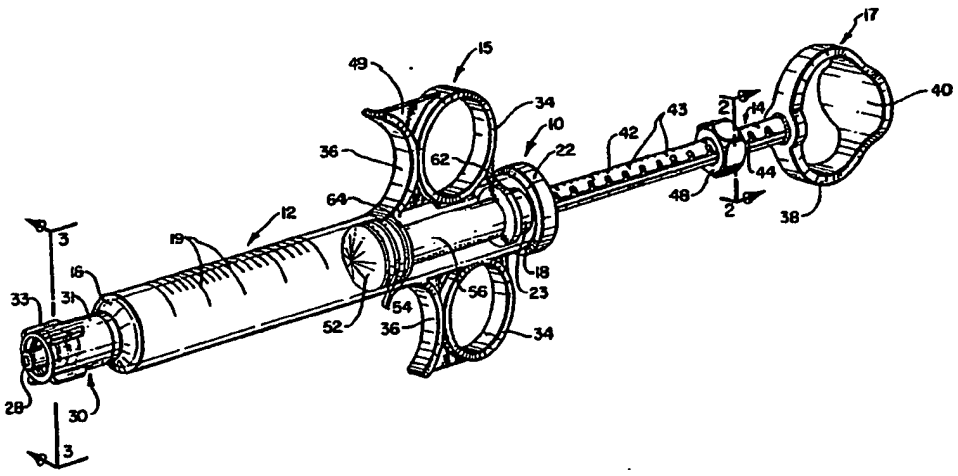

(57) Abstract

A disposable medical control syringe (10) has a barrel (12) fabricated from a transparent plastic material and is provided with a pair of integral finger loops (34) and wing grips (36) to facilitate alternate ways of gripping and applying force to the syringe plunger (14). The plunger (14) has a resilient sealing tip (52) in slidable sealing engagement with the wall of the cylindrical bore of the barrel. First and second stabilizing disks (62, 64) are provided on the plunger to maintain the plunger in coaxial alignment as it is pushed through the barrel. A collar (56) on the plunger spaces the sealing tip (52) slightly forward of the finger loops (34) and wing grips (36). The plunger stem (42) is also provided with a thumb loop (38) having a palm rest (40) as well as a notched portion (44) arranged along its length. A locking nut (48) is provided which engages the notched portion to selectively limit the movement of the plunger into the bore. The leading end of the syringe barrel is connected to a medical device (such as a catheter manifold) by way of a rotatable luer lock connector (30) which is mounted on the body so it may be rotated independently of the body.

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DISPOSABLE CONTROL SYRINGE

BACKGROUND

1

1. The Field of the Invention.

This invention relates to disposable medical syringes. More particularly, the present invention relates to a disposable control syringe.

2. The Background Art.

The customary hypodermic syringe and needle used to inject fluids into the human body is familiar to both medical professionals and the general public. However, syringes have many other uses in modern medicine besides intravenous or intramuscular injection of medication. For example, "control" syringes are known in the art, and are used for a variety of purposes. A control syringe capable of holding many milliliters of fluid (1 cc to 12 cc or more in contrast to the 0.5 ml to 2 ml capacity of hypodermic syringes) must be capable of providing a relatively high pressure and rapid delivery of injectate. Further, the amount of injectate as well as the handling and manipulation of the syringe must be easily and precisely controllable.

For example, during angiographic procedures it is often necessary when using a control syringe to inject up to 12 cc of contrast media per injection. During angiographic injections, the flowing contrast media in the arteries or heart chambers is viewed under fluoroscopy. The injection of the contrast media allows the arteries and heart action, which

are not ordinarily visible on an X-ray film, to become observable. During angiographic procedures both the rate of injection and the amount of contrast media which is injected must be carefully controlled.

As another example of the need for control syringes, during procedures intended to measure cardiac output using thermodilution methods, a bolus of liquid colder than body temperature is injected into the heart by way of a catheter lumen. The change in temperature of the blood after it travels through the heart is then measured using a thermistor mounted on the end of the catheter. The amount of cold liquid injected into the catheter must be carefully controlled in order for the cardiac output to be measured accurately by the temperature change occurring in the blood.

As a further example, many catheterization procedures require that a balloon located somewhere along the length of the catheter be inflated with a liquid. In order to inflate the balloon, a syringe is filled with the liquid which is injected into the catheter lumen leading to the balloon. Importantly, the amount of fluid must be carefully controlled and must never exceed a predetermined amount or the possibility arises that the catheter balloon may rupture with potentially serious consequences.

Initially, control syringes which were used in the art were fabricated from stainless steel and glass. While these kinds of syringes provided a rugged, durable construction, they also suffered from the disadvantage that they were very

costly devices, they were difficult to manufacture, and there was always the attendant problem of having to sterilize the devices after use, with the further possibility of contamination if sterilization was not properly carried out. While the rugged and durable nature of these devices was certainly an advantage (particularly given the fact that control syringes are typically used in environments where significant pressure is often exerted on the lunger, even to the point where a physician will use two hands to push the plunger into the syringe barrel), the mentioned disadvantages represented significant drawbacks to this type of device.

With the improvement in biomedical materials and fabrication methods arising in connection with low-cost plastic medical devices, there has been a tendency to replace the steel and glass control syringes previously used in the art with syringes made from plastic materials which are inexpensive enough to be disposable. However, while these disposable control syringes have solved some of the problems which were experienced in connection with the glass and stainless steel syringes, such as elimination of the need for sterilization and reduction in cost of the device, the disposable syringes have, on the other hand, suffered a number of significant disadvantages of their own.

For example, many of the disposable control syringes which are in use today lack the rugged construction which is required to withstand the rigors inherent in many of the medical applications in which they are used. It is not

uncommon for such syringes to break at the point of connection where the syringe is attached to a device, such as a catheter manifold. Further, typical plungers of control syringes presently in use in the art lack the required rigidity and strength to withstand significant mechanical pressure when a physician uses one or even both hands to bear down on the plunger of the syringe when required to do so in order to inject the fluid. In such situations, it may not be uncommon for the syringe plunger to bend, which may result in binding, breakage or leaking of fluid out of the syringe barrel.

Still further, some disposable control syringes suffer from other design inadequacies such as partially occluding the plunger of the syringe so that the person using the syringe cannot view the entire length of the barrel which contains fluid to be injected. Visual inspection of the barrel is an important feature since one must ascertain that no air bubbles are present, otherwise the potential danger of injecting air into a vessel may be present.

Other design disadvantages which have been observed with some devices in use in the art include the inability to precisely control the amount of injectate which is to be infused from the syringe, as well as providing insufficient mechanical support on the syringe barrel and plunger to permit the necessary pressures to be applied in an easy and comfortable fashion. Still further, some control syringes in use in the art even allow the plunger to be inadvertently

pulled out of the syringe barrel, which can a particularly aggravating occurrence when filling the syringe.

BRIEF SUMMARY AND OBJECTS OF THE INVENTION

In view of the problems experienced with the previously available control syringes, it is an overall object of the present invention to provide a medical control syringe which may be fabricated using low cost materials and techniques so as to be disposable after a single use, but which is still rugged and durable enough to withstand the rigors required of such syringes.

More specifically, one object of the present invention is to provide a disposable control syringe wherein the plunger is designed so that bending is minimized throughout the plunger's movement through the syringe barrel, as well as assuring that the plunger's movement is smooth and does not bind.

Another object of the present invention is to provide a disposable control syringe wherein a locking mechanism is provided to preset and hence accurately control the maximum amount of fluid which can be injected, and which locking mechanism can be smoothly adjusted and easily snapped into place.

Still another object of the present invention is to provide a disposable control syringe which is provided with a structure which securely connects the syringe to a medical device such as a catheter manifold, which prevents breakage

or inadvertent disconnection, and which is sufficiently strong to still allow the syringe body to be rotated for easily orienting the syringe so that it can be conveniently grasped for use.

Yet another object of the present invention is to provide a disposable control syringe wherein a structure is provided so that the plunger is restrained to prevent its complete removal from the syringe barrel while filling the barrel.

Still another object of the invention is to provide a disposable control syringe wherein essentially the entire length of the barrel of the syringe which contains fluid to be injected is visible so as to permit visual inspection of the fluid being injected.

Still another important object of the present invention is to provide a disposable control syringe which is provided with appropriate structure for gripping the syringe so that application of the necessary force on the syringe plunger can be conveniently applied using any of several desired techniques, including application of force on the syringe plunger using two hands, or in the alternative, using one hand, and by application of the force using the thumb or the palm of the hand.

Additional objects and advantages of the invention will be apparent from the drawings, description and appended claims which follow, or may be learned by the practice of the invention.

Consistent with the foregoing objects, the present invention comprises a medical control syringe which provides the advantage of being of low enough cost to be disposable after a single use, while still incorporating the desirable features and advantages of a rugged, durable syringe that can withstand the rigors required in typical applications for such syringes, as explained above. The control syringe of the present invention comprises a barrel fabricated from a hard, polycarbonate plastic which is highly transparent to permit visual inspection of the fluid held within the syringe barrel. Both finger loops and wing grips are disposed on the sides of the barrel to allow the user to grasp the barrel in a variety of ways. A rigid, ABS plastic plunger is positioned within the syringe barrel. The leading end of the plunger is provided with a collar to space the tip of the plunger slightly forward of the grips, thus ensuring that injectate will always be forward of the point where the control syringe is grasped, and thus susceptible to visual inspection. A stabilizing disc on the collar and an end cap on the barrel cooperate to provide plunger stability so as to minimize bending of the plunger while it is being pushed through the barrel. The cap also prevents the plunger from being inadvertently removed from the barrel when it is filled.

The plunger is provided with a releasable locking ring which may be preset to control the maximum amount of fluid which can be injected. A rotatable luer connector is provided on the barrel to connect the syringe to a medical device such

as a catheter manifold. The connector is preferably fabricated so that the body of the syringe may be rotated without loosening the connector or damaging the syringe while it is connected to the manifold, while still providing a mechanically stable attachment to the manifold. The plunger is also provided with a thumb loop having a palm rest to facilitate applying hand pressure using any of several alternative techniques.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of the presently preferred embodiment of the present invention.

Figure 2 is a cross-sectional view taken along line 2-2 of Figure 1.

Figure 3 is an elevational cross-sectional view of the embodiment of Figure 1, showing the plunger fully retracted.

Figure 3A is an enlarged portion of Figure 3.

Figure 4 is an exploded perspective view of the embodiment of Figure 1.

Figures 5A - 5C are perspective views which schematically illustrate alternative ways of grasping the control syringe of the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENT

Referring first to Figure 1, the control syringe of the present invention is generally designated at 10. The control syringe 10 is comprised of generally two main components. The

first is a barrel means for holding injectate which is to be expelled. In the illustrated embodiment the barrel means is comprised of a barrel assembly generally designated 12. The other main component of the control syringe is a plunger means which is slidably engaged within the barrel means. The plunger means is comprised of a plunger assembly generally designated at 14.

As shown best in Figure 3, the barrel assembly 12 is comprised of a cylindrical barrel 13 which has formed through the center of the barrel a bore 20. Preferably, the barrel 13 is constructed from material that is highly visually transparent such as polycarbonate plastic or other material which is highly transparent and yet which is also preferably low cost. As hereinafter more fully explained, it is especially desirable that at least the leading end of the barrel 13 be sufficiently visually transparent as to permit inspection of the contents of the barrel. This provides the important safety feature that air bubbles will be readily ascertained so as not to be expelled into the patient when injecting the fluid from the syringe. In the illustrated embodiment of Figure 3, the visually transparent leading end of control syringe 10 is schematically represented by the distance "X" as shown at reference numeral 60.

With further reference to Figures 3 and 4, the barrel assembly 12 has at its forward end a conically shaped portion 16 which terminates in a cylinder 35. At the base of cylinder 35 there is a circular platform 47. The other end of cylinder

35 terminates in a smaller cylinder 39, over which a rubber O-ring 37 fits. O-ring 37 assures a fluid-tight seal between luer connector 30 and cylinder 35 onto which connector 30 fits.

A rotatable female luer connector 30 with central cylindrical shaft 28 is provided with an extended base 31 which snaps onto the cylinder 35. Bore 26 through the center of cylinders 35, 39 and shaft 28 provides a passageway through which injectate is expelled into a catheter manifold. A locking ring 45 on cylinder 35 is designed to mate with a corresponding groove formed on the inside surface of base 31.

The female luer connector 30 is adapted to rotate around cylinder 35 so as to provide a rotatable connector means for permitting rotation of the entire syringe when connected to a stationary device such as a manifold from which the fluid can be dispensed through appropriate catheter lines into a patient. By providing a rotatable connector means as described, the control syringe of the present invention can be quickly and easily oriented by rotating the syringe so that the physician can grasp the syringe in the most convenient manner thereby optimizing the application of force and facilitating more accurate control of the fluid as it is dispensed from the syringe.

Importantly, the cylinder 35 and platform 47 serve as a means for reinforcing and stabilizing the rotatable luer connector 30 when connected to a catheter manifold. Platform 47 provides a flat, uniform support for base 31. Since the

end 16 of syringe barrel 13 is conical, without platform 47 the base 31 of luer connector 30 would not have adequate support, permitting undesired movement at the point of connection between luer connector 30 and barrel 13. Cylinder 35 further provides reinforcement between luer connector 30 and the end of the syringe barrel 13. Base 31 of luer connector 30 and reinforcing cylinder 35 are designed to provide a good friction fit. Thus, syringe barrel 13 will be held in a desired position unless rotated in relation to luer connector 30. Rotatable female luer connector 30 is also preferably fabricated from polycarbonate plastic so as to provide sufficient rigidity and strength to resist breakage and/or inadvertent disconnection of the control syringe when connected to a device such as a catheter manifold.

With further reference to Figures 1 and 3, the barrel assembly 12 further comprises an end cap 22 which snaps onto a lip 19 at the trailing end 18 of the syringe barrel 13. The end cap 22 serves as a means for enclosing the trailing end of the syringe barrel 13, and is provided with a diametrally reduced collar 23 having an opening 24 through which the syringe plunger may slide back and forth when actuating the plunger.

A variable grip means is generally designated at reference numerals 15 and 17, and is designed to permit the syringe to be grasped by a physician in any one of several different manners. As shown in Figures 1 and 3, the variable grip means comprises, for example, a pair of wing grips 36 as

well as an adjacent pair of finger loops 34, and a thumb loop 38 having a flattened palm member 40. Webbing 49 strengthens the grips 36 and loops 34. As shown best in Figures 5A - 5C, the variable grip means 15 and 17 permit either the wing grips 36 to be used, or the finger loops 34 to be used, or a combination of the two when using both hands to apply force to the plunger, as well as providing for actuation of the plunger using the thumb or palm.

As shown in Figure 3, the syringe assembly generally designated 14 is comprised of an elongated stem 42. The stem has a notched portion provided along the length thereof, with the notches being illustrated as at reference numeral 44. A nut 48 is situated on the stem 42 and is used for limiting movement of the stem 42 when actuating the plunger such that a controlled amount of fluid can be expelled from the syringe depending upon placement of the nut 42 along the notched portion of the stem. Importantly, stem 42 is rounded and smooth so that it does not bind when moving through opening 24 of collar 23 on the end cap 22. Furthermore, locking nut 48 is designed so that a friction fit is provided when nut 48 is on stem 42. This prevents nut 48 from sliding up and down on stem 42 and thus getting in the way when nut 48 is not in use.

The cross-sectional view of Figure 2 best illustrates the manner in which the nut 48 can be used as a means for limiting movement of the plunger to any of several selected positions relative to the syringe barrel. Locking nut 48 comprises a

protruding member 50 which extends inwardly so as to engage the notches 44 when the nut is rotated counter-clockwise in reference to the view of Figure 2. When the nut 48 is rotated clockwise in reference to Figure 2, the protruding member moves to the position illustrated at 51 (shown in dashed lines) so that the protruding member 50 slides along the slot 46 which is formed adjacent the notched portion of stem 42.

Thus, by rotating the nut 48 so that the protruding member 50 engages slot 46, nut 48 can be moved to any desired position along the length of stem 42. The nut 48 can then be rotated as described above so that it snaps into and engages the selected notch at the desired position, thereby providing the means for limiting movement of the plunger when pushing the plunger through the syringe. Member 50, as seen best in Figure 3A, snaps into the notch, and is firmly held there by means of rounded protrusions 53 that are formed at the entrance to each notch.

Also provided along the notched portion are markings which correspond to the volume of fluid to be expelled from the syringe barrel. For example, the markings 43 on the notched portion can conveniently indicate the selected positions along the stem 42 which would fix the position of the locking nut 48 so as to permit, for example, increments of 1 cc, up to 12 cc, to be injected. Also, note that corresponding markings are provided on the barrel of the syringe as indicated at reference numeral 19. Barrel markings 19 permit the amount of fluid to be injected into the patient

to be carefully monitored irrespective of whether the locking nut 48 is used to limit movement of the plunger or not.

The leading end of the plunger assembly 14 is comprised of a tip 52 which serves as a means for establishing a fluid-tight seal within the barrel such that the injectate or fluid within the barrel will not flow past the tip 52. The tip 52 is preferably formed of a rubber-like material which will provide the needed fluid-tight fit while still permitting the plunger to slide freely back and forth inside the barrel. In the illustrated embodiment, as shown best in Figure 3, the rubber tip 52 fits over a disk 51 which is provided at the end of the plunger assembly 14.

At the end of the rubber tip 52 there is a second, diametrally enlarged disk 64. A cylindrical collar 56 extends from disk 64 at one end thereof to a disk 62 at the other end thereof. The collar 56 serves as a means for spacing the tip 52 a selected maximum distance from the end cap 22 so that the tip 52 will be slightly forward of the wing grips 36 when the plunger assembly 14 is fully retracted and the barrel 13 is filled with injectate.

For example, as shown in Figure 3, when the plunger assembly 14 is fully retracted so as to permit the barrel of the syringe to be completely filled with injectate, note that the collar 56 serves to space the tip 52 a selected maximum distance which is indicated by the distance "Y" as designated at reference numeral 68 such that the tip 52 will be situated slightly forward of wing grips 36. Importantly, this assures

that the entire leading end 60 of syringe barrel 13 can be quickly visually inspected to make sure that there are no bubbles contained within the fluid to be injected into the patient.

Furthermore, it will also be appreciated with reference to Figure 3 that the disks 64 and 62 are separated by a selected maximum distance which is illustrated by the distance "Z" as indicated at reference numeral 58 in Figure 3. By making sure that the disk 62 is spaced by this maximum distance Z from the tip 52 of the syringe plunger, the disk 62 serves as a means for stabilizing the stem 42 of the plunger assembly as the plunger is pushed through the barrel of the syringe.

This stabilizing function results because the disk 62 helps to impart increased rigidity to the stem 42 and helps to prevent bending of the stem 42 by engaging bore 20 and maintaining the stem 42 in coaxial alignment with the center of the syringe barrel as the plunger is pushed through the barrel. Further stability is provided by means of the collar 23 (see Fig. 1) situated in the end cap 22.

Thus, as will be appreciated with reference to Figure 3, essentially three separate points of stability are provided by means of the structure of the plunger assembly, the three points being the disk 64, disk 62, and the collar 23 through which the stem 42 moves. In this manner, the two stabilizing disks 64, 62, as well as the support provided through the opening 24 of collar 23 all help to prevent bending so as to

maintain the syringe stem in coaxial alignment with the center of the syringe barrel as force is applied to the stem for purposes of dispensing the injectate or fluid contained in the syringe. Preferably, with the exception of cap 22, which is made of low-density polyethelene plastic, the entire plunger assembly 14 is fabricated from a hard plastic material such as ABS to provide further rigidity and strength to the overall assembly.

The exploded perspective view of Figure 4 serves to illustrate the preferred method of assembly of the control syringe. The locking nut 48 and end cap 22 are placed onto the stem 42, and collar 56 is then bonded onto the end of stem 42. The rubber tip 52 is then placed over the end of disk 51 and the plunger assembly is then inserted into the barrel 13 of the syringe, and end cap 22 is shaped onto lip 19 of the syringe barrel 13. O-ring 37 is placed over cylinder 39, and then luer connector 30 is snapped onto reinforcing cylinder 35 and secured by locking ring 45.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed and desired to be secured by United States Letters Patent is:

1. A medical control syringe for use in expelling an injectate in response to application of force applied by hand, said syringe comprising:

(a) barrel means for holding said injectate, said barrel means comprising:

(1) a visually transparent leading end through which injectate is expelled;

(2) a trailing end comprising a cap means for enclosing said trailing end of said barrel means; and

(3) grip means for grasping said barrel means when injecting said injectate; and

(b) plunger means slidably engaged within said barrel means and comprising:

(1) a leading end with a tip means for establishing a fluid-tight seal within said barrel means such that said injectate, when drawn into said barrel means, will not flow past said tip means;

(2) a trailing end projecting through said cap means so as to extend beyond the trailing end of said barrel means to permit application of force thereto by a user's hand so as to move said plunger means through said barrel means in response to said force; and

(3) collar means disposed on said plunger means intermediate said leading and trailing ends of the plunger means, said collar means spacing said tip means a selected maximum distance from said cap means so that said cap means will be slightly forward of said grip means when said plunger means is fully retracted and said barrel means is filled with injectate, thereby assuring visual inspection of the entire amount of injectate to be expelled from said syringe.

2. A syringe as defined in claim 1 further comprising rotatable connector means, disposed at said leading end of said barrel means, for permitting rotation of said syringe when connected to a manifold device.

3. A syringe as defined in claim 2 wherein said connector means comprises a luer connector.

4. A syringe as defined in claim 3 further comprising reinforcing and stabilizing means for connecting said luer connector to said leading end of the barrel means.

5. A syringe as defined in claim 4 wherein said reinforcing and stabilizing means comprises a platform formed at said leading end of said barrel means, said platform providing an essentially flat surface onto which said luer connector is seated, and said reinforcing and stabilizing means further comprising a cylinder over which said luer connector fits.

6. A syringe as defined in claim 5 wherein said reinforcing and stabilizing means further comprises an O-ring for providing a fluid-tight seal between said luer connector and said reinforcing cylinder over which said luer connector fits.

7. A syringe as defined in claim 1 further comprising lock means for limiting movement of said plunger means to any of several selected positions relative to said barrel means, whereby the amount of injectate expelled by movement of said plunger means is automatically controlled.

8. A syringe as defined in claim 7 wherein said lock means comprises a notched portion provided along the length of said plunger means intermediate said collar and said trailing end of the plunger means, and a lock nut for engaging said notched portion rearward of said cap means.

9. A syringe as defined in claim 1 wherein said grip means comprises means for accommodating application of said hand force by any one of several different methods of application.

10. A syringe as defined in claim 9 wherein said grip means comprises:

a pair of finger loops disposed on said barrel means;

a pair of wing grips disposed on said barrel means adjacent said finger loops; and

a thumb loop disposed at said trailing end of the plunger means, said thumb loop comprising a flattened palm member.

11. A syringe as defined in claim 1 further comprising a stabilizing disc disposed on said collar means, said disc being separated by a selected maximum distance from said tip means, and cooperating with said cap means so as to provide in combination therewith a means for holding said plunger means essentially in coaxial alignment with the center of said barrel means as said plunger means is moved through the barrel means.

12. A medical control syringe for use in expelling an injectate in response to application of force applied by hand, said syringe comprising:

an elongated cylindrical barrel comprising an interior bore therethrough and having a leading end through which injectate is expelled and a trailing end;

a cap means for enclosing said trailing end of said barrel;

an elongated generally cylindrical plunger coaxially aligned with said bore and comprising a leading end having a fluid-tight seal at the tip thereof, and a trailing end projecting through said cap so as to extend beyond the trailing end of said barrel to permit application of force thereto by a user's hand so as to move said plunger coaxially through said bore of the barrel in response to said force; and

a stabilizing disc disposed on said plunger intermediate said tip and said trailing end of the plunger, said stabilizing disc being separated from said tip by a selected maximum distance, said disc and said cap together providing a means for holding the plunger in essentially coaxial alignment within the center of said bore as the plunger is moved therethrough to expel said injectate, said stabilizing disc engaging an inside surface of said barrel defined by said bore.

13. A syringe as defined in claim 12 further comprising variable grip means for accommodating application of said hand force by any one of several different methods of application.

14. A syringe as defined in claim 13 further comprising a diametrally enlarged collar formed on said plunger behind said tip means, said collar having sufficient length such that when said plunger is completely withdrawn a trailing end of said collar will engage said cap so as to space said tip slightly forward of said grip means, and wherein said leading end of said barrel extends up to said grip means and is visually transparent, whereby the entire amount of injectate to be expelled from said syringe is susceptible to visual inspection.

15. A syringe as defined in claim 14 wherein said variable grip means comprises:

a pair of finger loops disposed on said barrel;

a pair of wing grips disposed on said barrel adjacent said finger loops; and

a thumb loop disposed at the trailing end of said plunger, said thumb loop comprising a flattened palm member.

16. A syringe as defined in claim 12 further comprising lock means for limiting movement of said plunger to any of several selected positions relative to said barrel, whereby the amount of injectate expelled by movement of said plunger is automatically controlled.

17. A syringe as defined in claim 16 wherein said lock means comprises a notched portion of said plunger along the length thereof intermediate said stabilizing disc and said trailing end of the plunger, and a slidable lock nut for engaging said notched portion intermediate said cap and said thumb loop.

18. A syringe as defined in claim 12 further comprising rotatable connector means disposed at the leading end of said barrel for permitting rotation of said syringe when connected to a manifold device.

19. A syringe as defined in claim 12 further comprising reinforcing and stabilizing means for connecting said luer connector to said leading end of the barrel means.

20. A syringe as defined in claim 19 wherein said reinforcing and stabilizing means comprises a platform formed at said leading end of said barrel means, said platform providing an essentially flat surface onto which said luer connector is seated, and said reinforcing and stabilizing means further comprising a cylinder over which said luer connector fits.

21. A syringe as defined in claim 20 wherein said reinforcing and stabilizing means further comprises an O-ring for providing a fluid-tight seal between said luer connector and said reinforcing cylinder over which said luer connector fits.

22. A syringe as defined in claim 12 further comprising a second stabilizing collar disposed on said plunger intermediate said tip and said stabilizing collar that is separated from said tip by said selected maximum distance.

23. A medical control syringe for use in expelling an injectate in response to application of force applied by hand, said syringe comprising:

an elongated cylindrical barrel comprising an interior bore therethrough and having a visually transparent leading end through which injectate is expelled, and a trailing end;

a cap means for enclosing said trailing end of said barrel;

an elongated generally cylindrical plunger coaxially aligned with said bore and comprising a leading end having a fluid-tight seal at the tip thereof, and a trailing end projecting through said cap so as to extend beyond the trailing end of said barrel to permit application in force thereto by a user's hand so as to move said plunger coaxially through said bore of the barrel in response to said force;

variable grip means disposed on said barrel for accommodating application of said hand force by any one of several different methods of application;

a diametrally enlarged collar disposed on said plunger intermediate said tip and the trailing end of said plunger, said collar having sufficient length to space said tip a selected maximum distance from said cap means so as to be slightly forward of said grip means when the plunger is fully retracted into said barrel and the barrel is filled with injectate;

a stabilizing disc separated from said tip by a selected maximum distance and disposed on said collar, said disc and said cap together providing a means for holding the plunger in essentially coaxially alignment within the center of said bore as the plunger is moved therethrough to expel said injectate;

rotatable connector means disposed at the leading end of said barrel for permitting rotation of said syringe when connected to a manifold device; and

lock means for limiting movement of said plunger to any of several selected positions relative to said barrel, whereby the amount of injectate expelled by movement of said plunger is automatically controlled.

24. A medical control syringe for use in expelling an injectate in response to application of force applied by hand, said syringe comprising:

an essentially elongated, cylindrical, transparent barrel comprising a leading and a trailing end thereof, and having a bore therethrough;

a rotatable luer connector disposed at the leading end of said barrel;

a cap disposed at the trailing end of said barrel for enclosing the bore at the trailing end thereof, said cap having a diametrally reduced central bore therethrough which is coaxially aligned with the bore of said barrel;

an elongated, essentially cylindrical plunger comprising a leading end with a tip situated within said bore of the plunger, said tip comprising a means for forming a fluid-tight seal within said bore, and said plunger extending for a portion of the length thereof through said diametrally reduced bore of said cap;

variable grip means comprising:

a pair of finger loops disposed on said barrel adjacent said cap;

a pair of wing grips disposed on said barrel adjacent said finger loops; and

a thumb loop disposed at the trailing end of said plunger, said thumb loop comprising a flattened palm member;

a diametrally enlarged collar disposed on said plunger immediately behind said tip, said collar having a sufficient length to space the tip slightly forward of said finger loops and wing grips when the plunger is fully withdrawn and the barrel is filled with injectate;

first and second stabilizing discs disposed on said collar, said first stabilizing disc being spaced from said tip by a selected maximum distance such that said plunger is held in essentially coaxial alignment within the center of said bore of the barrel as the plunger is moved through the bore of said barrel, and said second stabilizing collar being positioned on said collar intermediate said first collar and said tip;

said plunger having a notched portion of the length thereof which extends through the diametrally reduced bore of said cap; and

a locking nut disposed on said notched portion of the plunger and movable so as to engage said cap at any one of several selected locations along said notched

portion of the plunger, whereby the amount of injectate expelled by said plunger is selectively varied by limiting movement of said plunger in relation to said cap when locked by said locking nut.

AMENDED CLAIMS

[received by the International Bureau on 18 August 1989 (18.08.89)
original claims 1 - 24 replaced by amended claims 1 - 18 (7 pages)]

1. A medical control syringe for use in expelling an injectate in response to application of force applied by hand, said syringe comprising:

(a) barrel means for holding the injectate;

(b) cap means for enclosing one end of said barrel means;

(c) plunger means slidably engaged within said barrel means for expelling the injectate in response to the force applied by hand to said plunger means;

(d) grip means for grasping said barrel means;

(e) tip means disposed on said plunger means for establishing a fluid-tight seal within said barrel means such that the injectate will not flow past said tip means;

(f) collar means disposed on said plunger means for spacing said tip means slightly forward of said grip means when said plunger means is fully retracted and said barrel means is filled with injectate; and

(g) stabilizing means, disposed on said plunger means intermediate said fluid-tight seal of said tip means and said cap means, for cooperating with said cap means so as to hold said plunger means in essentially coaxial alignment within the center of said barrel means as said plunger means is moved therethrough to expel the injectate.

2. A syringe as defined in claim 1 further comprising rotatable connector means for permitting rotation of said syringe when connected to a manifold device.

3. A syringe as defined in claim 2 further comprising reinforcing and stabilizing means for connecting said rotatable connector means to said means.

4. A syringe as defined in claim 1 further comprising lock means for limiting movement of said plunger means to any of several selected positions relative to said barrel means, whereby the amount of injectate expelled by movement of said plunger means is automatically controlled.

5. A syringe as defined in claim 4 wherein said lock means comprises a notched portion provided along the length of said plunger means and a lock nut for engaging said notched portion rearward of said cap means.

6. A syringe as defined in claim 1 wherein said grip means comprises means for accommodating application of said hand force by any one of several different methods of application.

7. A syringe as defined in claim 6 wherein said grip means comprises:

a pair of finger loops disposed on said barrel means;

a pair of wing grips disposed on said barrel means adjacent said finger loops;

a thumb loop disposed on said plunger means, a portion of said thumb loop being flattened so as to form a palm member on said thumb loop.

8. A medical control syringe for use in expelling an injectate in response to application of force applied by hand, said syringe comprising:

an elongated cylindrical barrel comprising an interior bore therethrough and having a leading end through which injectate is expelled and a trailing end;

a cap means for enclosing said trailing end of said barrel;

an elongated generally cylindrical plunger coaxially aligned with said bore and comprising a leading end having a fluid-tight seal at the tip thereof, and a trailing end projecting through said cap means so as to extend beyond the trailing end of said barrel to permit application of force thereto by a user's hand so as to move said plunger coaxially through said bore of the barrel in response to the force; and

a stabilizing means disposed on said plunger intermediate said fluid-tight seal of said tip and said trailing end of the plunger for cooperating with said cap means so as to hold said plunger in essentially coaxial alignment within the center of said bore as the plunger is moved therethrough to expel the injectate.

9. A syringe as defined in claim 8 further comprising variable grip means disposed on said barrel for accommodating application of the hand force by any one of several different methods of application.

10. A syringe as defined in claim 9 further comprising a diametrally enlarged collar formed on said plunger behind said tip, said collar having sufficient length such that when said plunger is completely withdrawn a trailing end of said collar will engage said cap means so as to space said tip slightly forward of said grip means, and wherein said leading end of said barrel extends up to said grip means and is visually transparent, whereby the entire amount of injectate to be expelled from said syringe is susceptible to visual inspection.

11. A syringe as defined in claim 10 wherein said variable grip means comprises:

a pair of finger loops disposed on said barrel means;

a pair of wing grips disposed on said barrel means adjacent said finger loops;

a thumb loop disposed on said plunger means, a portion of said thumb loop being flattened so as to form a palm member on said thumb loop.

12. A syringe as defined in claim 8 further comprising lock means for limiting movement of said plunger to any of several selected positions relative to said barrel, whereby the amount of injectate expelled by movement of said plunger is automatically controlled.

13. A syringe as defined in claim 12 wherein said lock means comprises a notched portion of said plunger along the length thereof intermediate said stabilizing means and said trailing end of the plunger, and a slidable lock nut for engaging said notched portion intermediate said cap means and said thumb loop.

14. A syringe as defined in claim 8 further comprising rotatable connector means disposed at the leading end of said barrel for permitting rotation of said syringe when connected to a manifold device.

15. A syringe as defined in claim 8 further comprising reinforcing and stabilizing means for connecting said rotatable connector means to said leading end of the barrel means.

16. A syringe as defined in claim 8 further comprising a second stabilizing means disposed on said plunger intermediate said tip and said diametrally enlarged collar.

17. A medical control syringe for use in expelling an injectate in response to application of force applied by hand, said syringe comprising:

an elongated cylindrical barrel comprising an interior bore therethrough and having a visually transparent leading end through which injectate is expelled, and a trailing end;

a cap means for enclosing said trailing end of said barrel;

an elongated generally cylindrical plunger comprising a leading end having a tip means for forming a fluid-tight seal, and a trailing end projecting through said cap so as to extend beyond the trailing end of said barrel to permit application of the force thereto by a user's hand so as to move said plunger coaxially through said bore of the barrel in response to said force;

variable grip means disposed on said barrel for accommodating application of the hand force by any one of several different methods of application;

a diametrally enlarged collar disposed on said plunger intermediate said fluid-tight seal of said tip means and the trailing end of said plunger, said collar having sufficient length to space said tip means slightly forward of said grip means when the plunger is fully retracted into said barrel and the barrel is filled with injectate;

a stabilizing means, disposed on said plunger intermediate said fluid-tight seal of said tip means

and said trailing end of the plunger, for cooperating with said cap means so as to hold said plunger in essentially coaxial alignment within the center of said bore as the plunger is moved therethrough to expel the injectate;

rotatable connector means disposed at the leading end of said barrel for permitting rotation of said syringe when connected to a manifold device; and

lock means for limiting movement of said plunger to any of several selected positions relative to said barrel, whereby the amount of injectate expelled by movement of said plunger is automatically controlled.

18. A medical control syringe for use in expelling an injectate in response to application of force applied by hand, said syringe comprising:

an essentially elongated, cylindrical, transparent barrel comprising a leading end and a trailing end thereof, and having a bore therethrough;

a luer connector disposed at the leading end of said barrel;

means for rotating said luer connector;

a cap disposed at the trailing end of said barrel for enclosing the bore at the trailing end thereof, said cap having a diametrally reduced central bore therethrough which is coaxially aligned with the bore of said barrel;

an elongated, essentially cylindrical plunger comprising a leading end with a tip situated within said bore of the plunger, said tip comprising a means for forming a fluid-tight seal within said bore, and said plunger extending for a portion of the length

thereof through said diametrally reduced bore of said cap;

variable grip means comprising:

a pair of finger loops disposed on said barrel means;

a pair of wing grips disposed on said barrel means adjacent said finger loops;

a thumb loop disposed on said plunger means, a portion of said thumb loop being flattened so as to form a palm member on said thumb loop.

a diametrally enlarged collar disposed on said plunger immediately behind said tip, said collar having a sufficient length to space the tip slightly forward of said finger loops and wing grips when the plunger is fully withdrawn and the barrel is filled with injectate;

first and second stabilizing means spaced one from the other and disposed on said collar for stabilizing said plunger so that said plunger is held in essentially coaxial alignment within the center of said bore of the barrel as the plunger is moved through the bore of said barrel;

said plunger having a notched portion of the length thereof which extends though the diametrally reduced bore of said cap; and

a locking nut disposed on said notched portion of the plunger and movable so as to engage said cap at any one of several selected locations along said notched portion of the plunger, whereby the amount of injectate expelled by said plunger is selectively varied by limiting movement of said plunger in relation to said cap when locked by said locking nut.

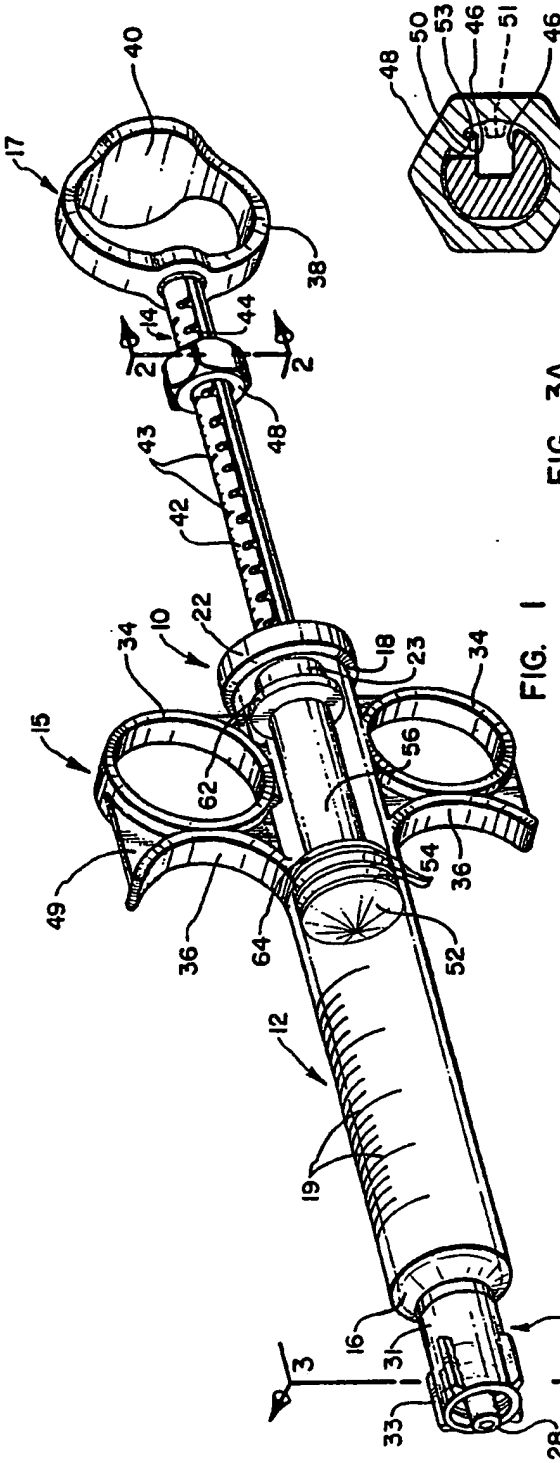

FIG. 1

FIG. 2

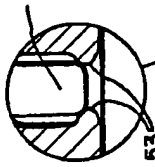

FIG. 3A

FIG. 3

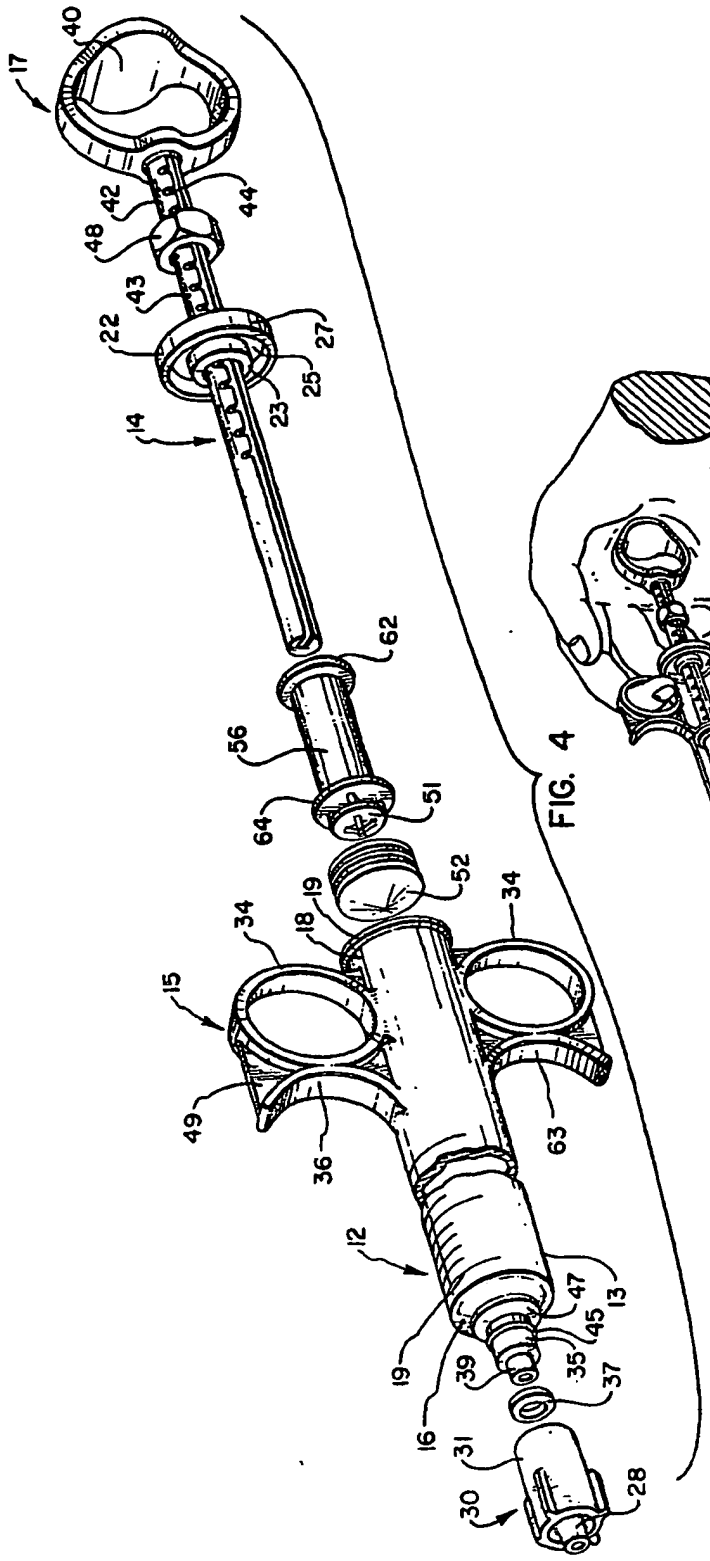

FIG. 4

FIG. 5B

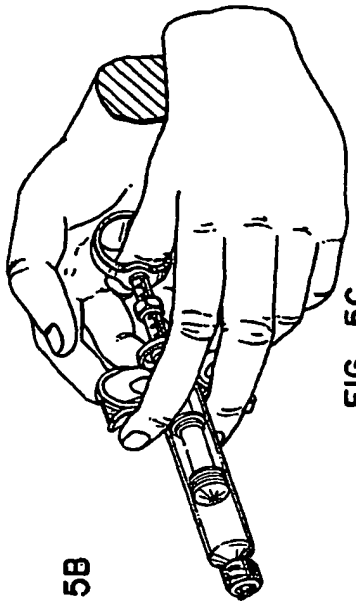

FIG. 5C

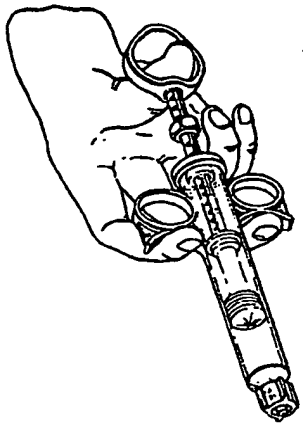

FIG. 5A

INTERNATIONAL SEARCH REPOR.

International Application No. PCT/US89/00577

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (4): A61M 5/00
U.S. Cl: 604/187

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	604/187, 208-211, 218, 222, 225, 227, 240-243

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	Product brochure of FMP for Control Ease Syringe, published prior to priority date although exact date unknown, see the entire document.	1-24
Y	Product brochure of COEUR Laboratories, Inc., published prior to priority date although exact date unknown, see the entire document.	1-11, 13-15, 23-24
Y	US, A, 2,656,836 (HICKEY) 27 October 1953 See the entire document.	2-6, 18-21, 23-24
Y	US, A, 3,491,757 (ARCE) 27 January 1970 See the entire document.	2-6, 18-21, 23-24
Y	US, A, 4,254,773 (WALDBILLIG) 10 March 1981 See the entire document.	2-6, 18-21, 23-24

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
26 April 1989	20 JUN 1989
International Searching Authority	**Signature of Authorized Officer**
ISA/US	K.M. Reichle K.M. Reichle